

request, advise interested persons of the data that will be needed. Where scientifically appropriate, the Center for Veterinary Medicine will allow the extrapolation of data from a major species to a minor species to satisfy the requirements of the act.

(Approved by the Office of Management and Budget under control number 0910-0032)

[40 FR 13825, Mar. 27, 1975]

EDITORIAL NOTE: For Federal Register citations affecting § 514.1, see the List of CFR Sections Affected in the Finding Aids section of this volume.

**§ 514.2 Applications for animal feeds bearing or containing new animal drugs.**

(a) Applications (Form FDA 1900) to be filed under section 512(m) of the act shall be completed, signed, and submitted in triplicate in the form described in paragraphs (b) and (c) of this section.

(b) Each application for a Type B or Type C medicated feed, as defined in § 558.3 of this chapter, shall include the following information:

(1) The name and address of the applicant.

(2) The registration number assigned pursuant to section 510 of the act and last date of registration of each mill.

(3) Whether the submission is an original or supplemental application.

(4) Identification of the Type A medicated article, as defined in § 558.3 of this chapter, used by generic name, potency, and manufacturer.

(5) The species of animal(s) for which the feed is intended.

(6) The form of feed to be produced, i.e., mash, meal crumbles, pellets, liquid, or other specified form.

(7) Whether the feed is a Type B or Type C medicated feed.

(8) Whether the feed is for sale or for own use (not for sale).

(9) Level of the drug(s) in the finished feed, and the amount of Type A medicated article per ton contained therein.

(10) Identification of the regulation(s) in subchapter E of this chapter on which approval relies.

(11) Labeling representative of each intended use as stated in the claim. Each generic label shall include the claim, drug level, mixing directions, feeding directions, caution and/or

warning statements, and any other special directions required by the published regulation. This shall consist of bag labels, invoice copy, bulk labels, and placards when applicable.

(12) A commitment to establish and maintain a program of sampling and analysis consisting of an assay of the first batch manufactured, followed thereafter by two samples at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. Reports of assays shall be kept on the premises for not less than 1 year after the date of manufacture of the medicated feed.

(13) A statement of the minimum and maximum assay value permitted from the labeled amount of the drug.

(14) Identification of the agent authorized to act on behalf of the applicant.

(15) The applicant's name, responsible individual's title and original signature, and date.

(c) Upon approval, one copy of the application will be signed by an authorized employee of the Food and Drug Administration designated by the Commissioner, and it will be returned to the applicant.

(d) Applications (Form FDA 1900) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

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[51 FR 7391, Mar. 3, 1986, as amended at 55 FR 14831, Apr. 19, 1990]

**§ 514.6 Amended applications.**

The applicant may submit an amendment to an application that is pending, including changes that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, and controls to preserve them, in which case the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the